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## REMARKS

Support for the amendment to claim 52 is found in prior claims 53, 54, and 55, the elements of which are now incorporated into claim 52. With regard to the equation in the last added element, applicant has inserted a comma to separate the "1-" and "2-" of the variable under the sigma sign and has changed the operand of the phi function in the compound variable being summed from an "f" to an "i". Support for the amendment to the equation is found throughout the specification as originally filed; see for instance the manifestation of the denominator in equation at page 47 as originally filed. Support for the amendment to claim 60 is a rearrangement of original words which serves to obviate a Section 112 rejection by more particularly pointing out and distinctly claiming the specific subject matter. No new matter is added by these amendments.

### Objection to the Title

Applicant thanks the Examiner for suggesting a title change. However, Applicant specifically begs that any correction of the title be deferred until the indication of allowable subject matter to avoid the possibility of unnecessary clerical work on the part of either applicant or the Office.

### Objections to Claims

Applicant submits that the objections to the claim 55 have been obviated by the amendment of the element originally found in claim 55 which has been added to claim 52.

### Rejection under 35 U.S.C. 101

Applicant traverses the Examiner's assertion that "the claimed Invention is directed to non-statutory subject matter" in rejection of the claims under 35 U.S.C. 101. Applicant specifically takes exception to the Examiner's statement that the methods of the invention do not have a "practical application" or that no "useful result produced/recited". The Examiner's attention is directed to the Manual of Patent Examining Procedure (MPEP) Section 2106, (IV)(B)(2)(b), *Computer-Related Processes Limited to a Practical Application in the Technological Arts*, where a statutory process "must be limited to a practical application of the

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abstract idea or mathematical algorithm in the technological arts". Under the same section, the Office offers this example:

"For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory."  
(Applicant's emphasis)

The claimed method involves a plurality of steps one of which employs a mathematical algorithm. In one sense any method involving a comparison involves a simple algorithm. The fact that the algorithm is expressed in words, e. g., comparing and selecting, rather than in a mathematical form does not make it any less an algorithm or make the method more or less patentable for want of utility. Further evidence that the particular algorithm found in the claims has a "practical application" is that such methods are widely used for identifying coding sequences of DNA.

Despite the many programs available for identifying coding sequence available at the time of the filing of this application, applicant is not aware that there were any programs available in the field of gene prediction that would *ab initio* solve frame shifts and that would integrate a bias function as described in this application. The methods of this invention describe a computational method to remove noise in a nucleic acid sequence, converting it to feature information, that is genes. See page 3, lines 28-29, as originally filed, for this excerpt:

"Described herein are methods, devices, and systems for analyzing the information content in nucleic acids."

The above comments illustrate but one of the unique and practical applications of the methods of the pending claims. In the event that the Examiner should persist in maintaining this Section 101 rejection, Applicant respectfully requests that the Examiner provide some evidence that a person having ordinary skill in the art would reasonably doubt the asserted practical utility.

In view of the above comments applicant respectfully requests that the Examiner reconsider and withdraw the Section 101 rejections.

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**Rejections under 35 U.S.C. 112, First Paragraph (written description)**

Applicant traverses the rejection under 35 U.S.C. 112, first paragraph, which is based on an implausible allegation that claims contain

“...subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.”

More specifically, with respect to the use of the term “selected” as found in pending claim 52, the Examiner alleges that the specification

“...makes no mention of whether this nucleotide was selected or randomly chosen.”

Applicant submits that the Examiner’s statement is a red herring and that the technician practicing the method will know whether it is selected. See, for example, the specification at the paragraph bridging pages 25 and 26, as originally filed, which states in pertinent part:

“...The nucleotide that is being examined is within the window, and the probability determinations set out in equations I, II, III, and IV are performed for the sequence in the window. The oligonucleotide probabilities are determined as before for the nucleic acid sequence within the window, probabilities for each of the states are determined for the nucleic acid sequence within the window, and those probabilities are assigned to the nucleotide within the window for which state probabilities are being determined, which, in a preferred embodiment, is the middle nucleotide. Another nucleotide is then examined, with the window shifted or redefined around the new nucleotide, and so on, until the final nucleotide in the nucleic acid sequence for which state probabilities are to be determined is reached.”

It is clear to a person of ordinary skill that almost any nucleotide in the window can be selected to start the method. Reconsideration and withdrawal of this rejection is respectfully requested.

Claim 52 stands rejected because the Examiner asserts that the phrase “bias function does not have the same value in all of said states for said selected nucleotide” broadens the scope of the claim beyond the support found in the specification. More specifically, the Examiner suggests that the phrase can be reasonably interpreted to mean all values must be different. Applicant submits that this rejection is obviated by the amendment to step (d) of claim 52 which more

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particularly points out that the bias function is at least different in one state within all of said states for the selected nucleotide. Reconsideration and withdrawal of this rejection is respectfully requested.

Claim 60 stands rejected because the Examiner asserts that there is no adequate support for the term "value" in the phrase "bias function has a value", which is particularly pointed out in the amendment to mean the value produced by said bias function. Applicant respectfully disagrees and cites the specification as originally filed for the definition of "bias" as it relates to "bias function":

"Bias' is a set of one or more values that are used in the Bias Function..."  
(page 18, line 17, Applicant's emphasis)

One of ordinary skill in the art would thus understand that the value produced by the bias function is the bias as represented by the conditions of the bias function. Further support is found in equations (V), (VI), (XIII), and (XXX) of the specification as originally filed. Reconsideration and withdrawal of this rejection is respectfully requested.

**Rejections under 35 U.S.C. 112, First Paragraph (Enablement)**

Applicant traverses the rejection of claims under 35 U.S.C., first paragraph,

"...as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention."

This rejection is superficial and unsupported by any evidence of record. Nonetheless, to expedite examination, Applicant directs the Examiner's attention to the Declaration of Jack E. Tabaska submitted herewith under 37 CFR 1.132 for the purpose of introducing evidence that the specification as originally filed would have enabled a person of ordinary skill in the art to practice the methods of the claims. In view of this declaration Applicant respectfully requests that this enablement rejection be reconsidered and withdrawn.

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**Rejections under 35 U.S.C. 112, Second Paragraph (Indefiniteness)**

Applicant traverses the multiple rejections of claims under 35 U.S.C. 112, second paragraph, for lacking definiteness. To expedite examination claims 47-48 and 50-51 are now cancelled. The response to indefiniteness rejections of other claims follows.

With specific regard to the rejection of claim 55 because of an alleged ambiguity in the algorithm for use of the symbol " $\phi(f)$ " in both the numerator and denominator, applicant submits the rejection has been obviated by cancellation of claim 55 and inserting into claim 52 an element having the algorithm with modification as found in the specification as originally filed. Applicant submits that the algorithm as originally stated would have been, and remains, clear to a person of ordinary skill in the art. However, to avoid ambiguity to those unskilled in the art Applicant has adopted an alternative form of the algorithm. Reconsideration and withdrawal of the Section 112 rejections for the basis is respectfully requested.

Applicant traverses the rejection of claim 55 based on the Examiner statement that there is a lack of clarity in the terms,  $f$ ,  $S$ ,  $P_t$ ,  $P_i$ , and  $\phi$ , as used in the equation. Since claim 55 is now cancelled but the algorithm is now added to claim 52, Applicant responds as the rejection may be maintained with respect to amended claim 52. In this regard Applicant respectfully disagrees with the basis for this rejection because the test for determining whether terms in a given claim are clear is whether a person skilled in the art would understand what is claimed. In this regard the Examiner's attention is directed to the decision of the Court of Appeals for the Federal Circuit (a tribunal charged with the judicial supervision of the Patent and Trademark Office, in the case of *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, where the court endorsed the Offices guidelines for determining definiteness of claims language by stating in pertinent part that *MPEP* § 2173.02 states

"[D]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

*Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991)

Although the specification does not define each of the following elements in dictionary manner, they are in fact defined as originally filed. See page 21 where it is clear that  $P_t$  means the probability of an oligonucleotide in a state, and  $f$  means an element of the set of states. See

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page 23, where it is clear that S means a nucleic acid sequence. See page 24 where it is clear that  $\phi$  means a bias function. Reconsideration and withdrawal of the rejection based on an alleged indefiniteness of element in the algorithm is respectfully requested.

Applicant submits that the rejection of claim 60 for indefiniteness in the phrase, "wherein said bias function has a value between 0.0 and 0.9, or greater than 1.1, in one or more of said states for said nucleotide" has been obviated by the amendment to claim 60. Reconsideration and withdrawal of the rejection of claim 60 is respectfully requested.

Applicant traverses the rejection of claim 57 based on an alleged lack of clarity over which nucleotide in a window of nucleotides is the middle nucleotide. Applicant directs the Examiner's attention to page 17 of the specification as originally filed which defines "middle nucleotide" in part as follows:

"The "middle nucleotide" in any given nucleic acid sequence or window is the nucleotide found at the numerical middle of the nucleic acid sequence or window, respectively, wherein the length of a nucleic acid sequence or window is the total number of nucleotides in the nucleic acid sequence of window. If the nucleic acid sequence or window has an even number of nucleotides, then the middle nucleotide can be either of the two nucleotides adjacent the numerical middle of the nucleic acid sequence or window."

In view of the specific definition Applicant respectfully requests that the indefiniteness rejection of claim 57 be reconsidered and withdrawn.

#### **Rejections under 35 U.S.C. 103(a)**

Applicant notes that claims 45-46, 48-54, and 56-60 were rejected under Section 103(a) as being obvious. Since the sole element of dependent claim 55 has been incorporated into the sole remaining independent claim 52, applicant submits that no obviousness rejections are outstanding in the claims as amended. Reconsideration and withdrawal of any section 103 rejection is respectfully requested.

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**Summary**

In view of the above amendment and comments addressing specific rejections and objections Applicant urges the Examiner to reconsider and withdraw the specific rejections and indicate allowance of the amended claims. If the Examiner has any questions regarding this application, the Examiner is encouraged to contact Applicants' undersigned agent at (860) 572-5217 (telephone) or (860) 572-5280 (fax).

Respectfully submitted,



Maria Margarita D. Unson  
Registration Number 53,711  
Agent for Applicants

Date: 29 January 2007

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

*In re:* Application of James D. McIninch  
Filed: February 11, 2004  
Title: Computational Nucleic Acid Coding and Feature Analysis  
U.S. Application No: 10/775,176  
Atty. Docket No: 16517

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Declaration Under 37 CFR 1.132

I, Jack E. Tabaska, declare that:

- I received my PhD in Molecular, Cellular, and Developmental Biology from the University of Colorado in 1996;
- From 1997 to 1999 I worked with Dr. Michael Zhang at Cold Spring Harbor Laboratory on computational approaches to signal identification and that I had several publications resulting from that work including Tabaska, JE and Zhang, MQ (1999), Gene 231: 77 – 86 and Tabaska, JE et al. (2001 Bioinformatics 17:602 – 607);
- Since 1999, I have been employed by Monsanto Company developing proprietary DNA sequence analysis software and using such software in DNA sequence analysis;
- I have read the description of the invention and claims disclosed in application Serial No. 10/775,176
- I have performed many times in my career the calculations of probabilities needed for practicing the methods of the invention as presently claimed in application Serial No. 10/775,176 and believe that such methods for calculating all of the probabilities needed for practicing the methods of this invention as presently claimed would have been well known to a person of ordinary skill in the art who is familiar with DNA sequence analysis and gene finding methods at the time the application was filed;



- It is my belief that devising alternatives to the algorithms for calculating probabilities used to define the present claims would be a trivial task in view of the disclosure in the specification;
- It is my belief that obtaining data from which to calculate the necessary probabilities for practicing the methods of this invention would not require undue experimentation, given the many millions of DNA sequences that were freely available to the public from sources such as GenBank at the time of filing;
- It is my belief that the illustrative examples provided in this application more than adequately guide those skilled in the art away from any possible ambiguity about how the necessary probability calculations should be performed;
- In summary, it is my professional opinion that the specification in this application provides to a person of ordinary skill in the art a complete and straightforward explanation of the invention and how to use the methods of the invention as set forth in the presently pending claims; and .
- I hereby declare that all of the above statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the united states code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed:  Date: 1/26/07

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